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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 2

Substance Abuse and Mental Health Services Administration; Confidentiality of Alcohol and Drug Abuse Patient Records

RIN: 0905-AD97

AGENCY: Substance Abuse and Mental Health Services Administration, PHS, HHS.

ACTION: Final rule.

SUMMARY: The Department published a notice of proposed rulemaking in the *Federal Register* at 59 FR 42561 (August 18, 1994) with corresponding corrections at 59 FR 45063 (August 31, 1994), which proposed a clarification to the "Confidentiality of Alcohol and Drug Abuse Patient Records" regulations codified at 42 CFR part 2. Specifically, the Department proposed to clarify that, as to general medical care facilities, these regulations cover only specialized individuals or units in such facilities that hold themselves out as providing and provide alcohol or drug abuse diagnosis, treatment or referral for treatment and which are federally assisted, directly or indirectly. The Secretary has considered the comments received during the comment period, and is amending the regulations.

EFFECTIVE DATE: June 5, 1995.

FOR FURTHER INFORMATION CONTACT: Sue Martone, SAMHSA, Room 12C15, 5600 Fishers Lane, Rockville, Maryland 20857, tel. (301) 443-4640.

SUPPLEMENTARY INFORMATION: The "Confidentiality of Alcohol and Drug Abuse Patient Records" regulations, 42 CFR part 2, implement section 543 of the Public Health Service Act, 42 U.S.C. § 290dd-2, as amended by section 131 of the ADAMHA Reorganization Act, Pub. L. 102-321 (July 10, 1992). The regulations were promulgated as a final rule on July 1, 1975 (40 FR 27802) and amended on June 9, 1987 (52 FR 21798). After considering the comments, the Department is revising the regulations to clarify the definition of "program."

Background of the Interim Final Rule and Summary of and Responses to Public Comments

A. Notice of Proposed Rulemaking

The notice of proposed rulemaking published at 59 FR 42561 (August 18,

1994) proposed to revise 42 CFR part 2 to clarify the ambiguity in the regulations regarding the definition of "program." This ambiguity was identified in the case *United States v. Eide*, 875 F.2d 1429, 1438 (9th Cir. 1989), where the court held that the Veterans Administration Medical Center's (VAMC) general emergency room is a "program" as defined by the regulations. In reaching this conclusion, the court relied on the clause that "[p]rogram means a person which in whole or in part holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment, or referral for treatment." *Id.* The court ruled that the VAMC was a "person" which is defined at section 2.12 to mean "an individual, * * * Federal, State or local government or any other legal entity," and concluded that "[a] hospital emergency room, while obviously also performing functions unrelated to drug abuse, serves as a vital first link in drug abuse diagnosis, treatment and referral." *Id.*

As indicated in the NPRM, the Department believed this interpretation too broadly defined the term "program" in the regulations. See 59 FR 42561, 42562. Accordingly, the Department proposed to clarify the definition of "program" in the regulations to ensure that it encompasses only (1) an individual or entity (other than a general medical facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or (2) an identified unit within a general medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or (3) medical personnel or other staff in a general medical care facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers.

B. Public Comments

Two commenters believed that the revised definition of "program" was too narrow. One of these commenters believed that the definition of "program" should include all physicians and other hospital and emergency room personnel who treat substance abusers. The other commenter believed that emergency room personnel should be covered by the regulations because they serve as an important source of referrals for substance abuse treatment. Both commenters believed that relief from the confidentiality rules could discourage persons who abuse

substances from seeking services for other medical problems.

It should be noted that the clarification which was proposed was the intent of the revisions made to the regulations in 1987. See 52 FR 21796, 21797 (June 9, 1987). As indicated in the NPRM, prior to the 1987 amendments, the regulations applied to any record relating to substance abuse whether the information was obtained from an emergency room, a general medical unit or a general practitioner so long as there was a Federal nexus. In 1987, however, it was the intent of the Department to limit the applicability of the regulations to specialized programs and personnel so as to simplify administration of the regulations. It was the Department's position that this limitation would not significantly affect the incentive to seek treatment provided by the confidentiality protection. See 52 FR at 21797. Furthermore, the Department questioned whether applicability of the regulations to general medical care facilities addressed the intent of Congress to enhance treatment incentives for alcohol and drug abuse, since many substance abuse patients are treated in a general medical care facility not because they have made a decision to seek substance abuse treatment, but because they have suffered a trauma or have an acute condition with a primary diagnosis of something other than substance abuse. *Id.*

The Department is not aware of any evidence that the narrowing of the applicability of the regulations in 1987 (at least for jurisdictions other than the Ninth Circuit) has adversely affected substance abusers from seeking treatment whether for substance abuse or other medical problems. The Department is also not persuaded that encompassing all health care facilities and providers who provide alcohol and drug abuse treatment only as an incident to the provision of general medical care is warranted in light of the economic impact such a regulation would have on a substantial number of facilities which do not specialize in substance abuse treatment, referral or diagnosis.

One Federal agency believed that the proposed definition of "program" does not provide sufficient guidance to law enforcement, particularly the phrase "holds itself out as * * *." That agency believed that the definition presents an opportunity for a practitioner who does not engage in substance treatment or referral for treatment, to designate himself or herself as a "program," thereby avoiding regulatory or investigative scrutiny.

It should be noted that, in the definition of a "program," a private sector practitioner must not only hold himself or herself out as providing such treatment, referral or diagnosis, but also must provide such treatment, referral or diagnosis. Therefore, even though a person may hold himself or herself out as providing substance abuse treatment, diagnosis or referral, that person would not constitute a program if he or she does not provide such treatment, diagnosis or referral.

It should also be noted that, even if the regulations do apply, the regulations do not bar investigative or regulatory scrutiny of such programs. Law enforcement agents may obtain a court order to place an undercover agent in a program, 42 CFR 2.67, or a court order directing a program to disclose patient identifying information for use of records to investigate or prosecute a program, 42 CFR 2.66.

This Federal agency also requested that the Department provide more guidance to law enforcement on the phrase "holds itself out as" so as to enable them to determine whether an investigation of a particular practitioner via patient records or undercover operations would require a court order. This agency suggested that the Department require private practitioners who provide such treatment, diagnosis or referral to indicate this through, for example, state licensing procedures, advertising or the posting of notice in their offices.

The Department believes that private practitioners may hold themselves out as providing substance abuse treatment, diagnosis or referral by the means described above. However, the primary purpose of the statute is to protect the confidentiality of alcohol and drug abuse patient records. The Department does not believe that requiring all programs to, for example, post notice in some conspicuous place (stating that they were subject to these regulations) is meaningful, since it does not necessarily mean that the regulations would not be applicable if such signs were not posted. Given their questionable value, such requirements would place an unnecessary burden on programs. Furthermore, federally assisted programs are to inform law enforcement officials who are seeking records that they are covered by the regulations and cannot provide patient records without a court order, thus placing such officials on notice.

Finally, although the law and the implementing regulations require that law enforcement officials take additional measures to obtain certain information (i.e., court orders to obtain

patient records or to place an undercover agent in a program), the Department believes that the narrowing of these regulations to specialized programs and practitioners should make it easier for such officials to identify "programs" to who these regulations are applicable and, thus, to obtain the relevant court orders.

Economic Impact

This rule does not have cost implications for the economy of \$100 million or otherwise meet the criteria for a major rule under Executive Order 12291, and therefore do not require a regulation impact analysis. Further, these regulations will not have a significant impact on a substantial number of small entities, and therefore do not require a regulatory flexibility analysis under the Regulatory Flexibility Act of 1980.

Federal Supremacy

These regulations are not intended to preempt the field of law which they cover to the exclusion of all State laws in that field. However, consistent with established principles of constitutional law, the Federal regulations will supersede State law to the extent that there is a conflict. See 42 CFR 2.20 for further discussion of the relationship between these regulations and State laws.

Paperwork Reduction Act

There are no new paperwork requirements subject to the Office of Management and Budget approval under the Paperwork Reduction Act of 1980.

List of Subjects in 42 CFR Part 2

Alcohol abuse, alcoholism, Confidentiality, Drug abuse, Health records, Privacy.

Dated: February 14, 1995.

Philip R. Lee,

Assistant Secretary for Health.

Approved: March 22, 1995.

Donna E. Shalala,

Secretary.

For the reasons set out in the preamble, part 2 of title 42, Code of Federal Regulations, is amended as follows:

PART 2—[AMENDED]

1. The authority citation for part 2 is revised to read as follows:

Authority: Sec. 408 of Pub. L. 92-255, 86 Stat. 79, as amended by sec. 303 (a), (b) of Pub. L. 93-282, 83 Stat. 137, 138; sec. 4(c)(5)(A) of Pub. L. 94-237, 90 Stat. 244; sec. 111(c)(3) of Pub. L. 94-581, 90 Stat. 2852;

sec. 509 of Pub. L. 96-88, 93 Stat. 695; sec. 973(d) of Pub. L. 97-35, 95 Stat. 598; and transferred to sec. 527 of the Public Health Service Act by sec. 2(b)(16)(B) of Pub. L. 98-24, 97 Stat. 182 and as amended by sec. 106 of Pub. L. 99-401, 100 Stat. 907 (42 U.S.C. 290ee-3) and sec. 333 of Pub. L. 91-616, 84 Stat. 1853, as amended by sec. 122(a) of Pub. L. 93-282, 88 Stat. 131; and sec. 111(c)(4) of Pub. L. 94-581, 90 Stat. 2852 and transferred to sec. 523 of the Public Health Service Act by sec. 2(b)(13) of Pub. L. 98-24, 97 Stat. 181 and as amended by sec. 106 of Pub. L. 99-401, 100 Stat. 907 (42 U.S.C. 290dd-3), as amended by sec. 131 of Pub. L. 102-321, 106 Stat. 368, (42 U.S.C. 290dd-2).

2. In § 2.11, the definition of *Program* is revised to read as follows:

§ 2.11 Definitions.

* * * * *

Program means:

(a) An individual or entity (other than a general medical care facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(b) An identified unit within a general medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or

(c) Medical personnel or other staff in a general medical care facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers. (See § 2.12(e)(1) for examples.)

* * * * *

3. Section 2.12(e)(1) is amended by adding the following sentence at the end to read as follows:

§ 2.12 Applicability.

* * * * *

(e) * * * (1) * * * However, these regulations would not apply, for example, to emergency room personnel who refer a patient to the intensive care unit for an apparent overdose, unless the primary function of such personnel is the provision of alcohol or drug abuse diagnosis, treatment or referral and they are identified as providing such services or the emergency room has promoted itself to the community as a provider of such services.

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